Remarks

Introduction

Claims 23-25 and 42-44 were pending. By way of this response, claim 23 has been amended, and claim 25 has been cancelled without prejudice. Support for the amendments to the claims can be found in the specification as filed, and care has been taken to avoid adding new matter. Accordingly, claims 23-24 and 42-44 are currently pending.

Claim Objections

Claim 23 was objected to for reciting "in the the samples".

Claim 23 has been amended by replacing the objected phrase with --in the samples--.

In view of the above, applicant submits the objection has been overcome.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 23-25 and 42-44 have been rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

Based on review of the Office Action, it appears that the rejection is based on the recitation of the word "or" instead of "and". Claim 23 has been amended to recite the word "and" instead of "or". Applicant submits that the presently claimed methods, which recite certain amounts of hyperglycosylated human chorionic gonadotrophin and human chorionic gonadotrophin are properly described in the specification of the present application, as acknowledged in the Office Action.

In view of the above, applicant submits that the rejection under 35 U.S.C. § 112, first paragraph has been overcome, and applicant respectfully requests withdrawal of the rejection.

Rejection Under 35 U.S.C. § 112, second paragraph

Claim 25 has been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite.

Claim 25 has been cancelled as set forth above.

Therefore, applicant submits the rejection under 35 U.S.C. § 112, second paragraph is moot.

Rejections Under 35 U.S.C. § 103

Claims 23-25, 42, and 43 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cole et al. (Clinical Chemistry Feb 2001; hereinafter Cole) in view of O'Connor et al. (U.S. 6,500,627; hereinafter O'Connor) in light of Birken et al. (2001; hereinafter Birken 2001) in view of Hochstrasser et al. (US 2003/0157580; hereinafter Hochstrasser) and Birken et al. (US 6,521,416; hereinafter Birken '416). Claim 44 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cole in view of O'Connor in light of Birken 2001 in view of Hochstrasser and Birken '416, and further in view of Campbell et al. (US 4,946,958; hereinafter Campbell).

Applicant traverses the rejections of the present claims.

The primary reference, Cole, is a review article discussing shortcomings of a number of publicly available assays used in the diagnosis and management of trophoblastic diseases. Many of the assays disclosed by Cole were associated with low or false-negative results and misdiagnosis of persistent disease (page 308, abstract, background). Cole specifically states that the "inability of commercial hCG tests to fully detect these hCG variants has led to failure to detect persistent or recurrent trophoblastic diseases, requiring urgent chemotherapy or surgery" (page 309, left column, 1st full paragraph, last sentence). The problem addressed by Cole is to examine the appropriateness of different hCG assays for monitoring patients with trophoblastic diseases (page 309, left column, 2nd full paragraph). Cole confirms the errors associated with a number of different assays, and states that "only the hCGbeta RIA and the DPC test effectively detected all of the hCG breakdown products or glycosylation variants (page 313, right column, 1st full paragraph). The hCGbeta RIA uses a polyclonal antibody to detect hCG and its variants (page 309, left column, 2nd full paragraph). The DPC assay is a total hCG test which attempts to detect hCG and its variants (page 310, right column, 1st paragraph). Thus, based on the teachings of Cole, one would conclude that broad spectrum antibodies that detect all of the variants of hCG are desired in diagnosing and managing trophoblastic disease. This is especially apparent since Cole discloses that assays with more specific antibodies result in substantial diagnostic errors.

The other references have been characterized in applicant's previous responses.

Applicant submits that a person of ordinary skill in the art would not be motivated to combine the teachings of O'Connor and Cole, let alone do so and obtain the presently claimed methods.

As understood by persons of ordinary skill in the art, prior to applicant's invention, it was believed that accurate diagnoses of trophoblast diseases depended on total hCG measurements. This is confirmed by the teachings of Cole which provide evidence that prior to applicant's invention, only assays that could measure total hCG were not associated with significant misdiagnoses.

Based on the cited references, a person of ordinary skill in the art would not be motivated to combine the teachings of O'Connor which discloses the use of monoclonal antibodies with the teachings of Cole directed to the use of broad spectrum antibodies, such as polyclonal antibodies. As understood by persons of ordinary skill in the art, monoclonal antibodies are highly specific antibodies. Thus, the use of monoclonal antibodies is contrary to the teachings of Cole which emphasize the importance of broad spectrum antibodies to detect hCG and all of its variants. Using monoclonal antibodies based on the teachings of Cole would lead a person of ordinary skill in the art to conclude that the chances of misdiagnosis would be increased since it would be more likely that different variants of hCG would not be detected. Since Cole is directed to using assays with reduced error rates and reduced misdiagnoses, it can be concluded that Cole actually teaches away from the use of monoclonal antibodies.

In addition, the added cost in terms of time and equipment to produce monoclonal antibodies relative to polyclonal antibodies can result in increased costs associated with the assays. These increased costs as well as complexities associated with producing monoclonal antibodies provide a further basis for a person of ordinary skill in the art to be unmotivated to combine the teachings of O'Connor with the teachings of Cole prior to applicant's invention.

Furthermore, applicant submits that the additional references cited in the Office Action do not provide any additional motivation to use monoclonal antibodies in the assays disclosed by Cole.

Thus, applicant submits that a person of ordinary skill in the art would not be motivated to combine the cited references, and therefore, the present claims are unobvious over the cited references.

Since claim 44 is dependent from claim 23, and since claim 23 is unobvious from the cited references, as discussed above, applicant submits that claim 44 is similarly unobvious over the cited references.

In view of the above, applicant submits that the present claims are unobvious from and patentable over the cited references, taken alone or in any combination, under 35 U.S.C. § 103.

Conclusion

In conclusion, applicant submits that each of the outstanding rejections have been overcome, and that the present claims are in condition for allowance, notice of which is respectfully requested. If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned representative invites the Examiner to telephone him at the number provided below.

Respectfully submitted,

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/Greg S. Hollrigel, Reg. # 45374/

Greg S. Hollrigel
Registration No. 45,374
Stout, Uxa, Buyan & Mullins, LLP
4 Venture, Suite 300
Irvine, California 92618
Telephone: 949-450-1750